

Department of Health and Mental Hygiene
Nelson Sabatini, Secretary

Community Health Administration
Diane Matuszak, M.D., M.P.H., Director

Epidemiology and Disease Control Program
John P. Krick, Ph.D., Director



MEMORANDUM

TO: Health Officers
Nursing Directors
Communicable Disease Directors
Environmental Health Directors
H.O.# 03-020

FROM: Shirin Badrtalei, MPH, Epidemiologist
Division of Outbreak Investigation

THROUGH: Leslie Edwards, MHS, Chief (Acting)
Division of Outbreak Investigation

DATE: April 1, 2003

SUBJECT: FDA Issues Public Health Advisory Regarding Labeling Changes for Lindane Products

This memo provides information on the FDA Health Advisory on the use of **Lindane Lotion and Lindane Shampoo** for the treatment of scabies and lice. There have been three main changes:

- I. New labeling includes a Boxed Warning**, highlighting the most important safety issues:
 - Lindane products have been, and continue to be, indicated as a second-line therapy for treatment of scabies and lice. Patients should only be treated with Lindane if other treatments are not tolerated or have failed
 - Lindane products are to be used with caution in patients who weigh less than approximately 110 pounds (50 kg). These products are not recommended for use in infants, and are contraindicated in premature infants.
- II. Addition of a Medication Guide**, which must be dispensed by pharmacists directly to the patient with each new prescription of Lindane Lotion or Lindane Shampoo.
- III. Additional Changes in the labeling address FDA concerns** of potential increased risk of adverse reactions associated with immuno-compromised patients, such as those with HIV infection, or patients on medications such as antidepressants.

If you have any questions about this memo, please contact Shirin Badrtalei at 410-767-0584.

cc: D. Matuszak, M.D., M.P.H. – DHMH/CHA
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